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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/068,804 05/14/98 MILLER

S 00786/292002

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EXAMINER

BASKAR, P

ART UNIT	PAPER NUMBER
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1645

18

DATE MAILED:

08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/068,804

Applicant(s)

Miller I, Samuel

Examiner

Padma Baskar

Group Art Unit

1645



☒ Responsive to communication(s) filed on Apr 24, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 17, 18, and 46-86 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 17, 18, and 46-86 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1645

RESPONSE TO AMENDMENT

1. Applicants amendment filed on 4/24/00 has been entered. Claims 1-16 have been canceled and new claims 46-86 have been added. Claims 46-86 and 17-18 are pending in the application. Upon further review the following new grounds of rejection have been set forth and the previous rejections are being maintained. Any inconvenience to the Applicant is regretted.

2. In view of applicant's arguments on record, examiner has withdrawn 112, first paragraph enablement rejection for claim 17.

New Rejections - 35 U.S.C. § 112

3. Claims 46-86 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no clear written description in the specification about SEQ.ID.NOS which are recited in claims 46-86 and 17. If applicant uses comprising language in the claims, it should be written what else the sequence contain besides the one is in the sequence listing? Do they have cDNA?

Claim 17 does not describe the usefulness of uptake of a bacterial cell by an epithelial cell and also administering this cell to a mammal would lead to what function? Since there is no clear description of the SEQ.ID.NO 1 and 2 this method needs to be written more clearly with specific use.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 46, 52, 58, 64, 70, 76 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46, 52, 58, 64, 70, 76 and 82 are rejected as being vague and indefinite "hybridizes under conditions of hybridization in 50% formamide at 42° and washing in 0.1X SSC at 65°"

What are these hybridizing conditions and which part of the sequence hybridizes to what? What are these sequences? What is the function of this hybridization? Page 5 of specification "for example", Are these the actual conditions used in this specification.

What is SSC? Full terminology should given when used for the first time in the claim.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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7. Claims 46-86 are rejected under 35 U.S.C. 102(a) as being anticipated by THE GENERAL HOSPITAL CORPORATION (WO95/02048).

Claims are directed to an isolated nucleic acid molecules encoding a Salmonella secreted protein.

WO 95/02098 discloses that Salmonella ~~secreted~~ protein secretion is dependent on the expression of PrgH gene (pages 5, 11, and 19). The prior anticipates the claimed invention.

8. Claims 46-86 and 17-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Hueck et al 1995 (Molecular Microbiology 18, 479-490).

Claims are directed to substantially pure DNA encoding a salmonella secreted protein comprises SspB, SspC, SspD and SspA genes, a cell which contains this gene, and a method for uptake of bacterial cell by an epithelial cell.

Hueck et al disclose substantially pure DNA encoding a Salmonella secreted protein, where the DNA comprises SspB, SspC, SspD and SspA genes (page 483, figure 4, page 485 figure 6). Invasion of HEp-2 cells with S.typhimurium discloses a cell which contains the DNA (page 482, 4th paragraph) because wild-type bacteria inherently contain all these genes. The prior art also discloses a method of inducing uptake of a bacterial cell by an epithelial cell by invasion assays (page 488). The prior art anticipates the claimed invention.

9. Claims 46-86 and 17-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Kaniga et al 1995 (Journal of Bacteriology, 177, 3965-3971).

Claims are directed to an isolated nucleic acid molecules comprising SEQ.ID.NOS 1, 5, 2 and 6 and a method for uptake of bacterial cell by an epithelial cell

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Kaniga et al discloses invasion of *Salmonella typhimurium* into epithelial cells (material and methods, invasion assays) and secretion of proteins SipB (SEQ.ID.NO 1 and 5 and SipC (page 3948, figure 4 and 5). These proteins are analogous to SspB, SspC. *Salmonella typhimurium* is a wild type bacteria and hence contains SspB, SspC, SspD and SspA genes (claims 46-86). The prior art anticipates the claimed invention. The prior art anticipates the claimed invention.

10. Claims 46-86 and 17-18 rejected under 35 U.S.C. 102(a) as being anticipated by Hermant et al 1995 (Molecular Microbiology, 17, 781-789).

Claims are directed to an isolated nucleic acid molecules comprising SEQ.ID.NOS 1, 5, 2, 6, 3, 7, 4 and 8 and a method for uptake of bacterial cell by an epithelial cell

Hermant et al discloses *Salmonella* entry into epithelial cell and the DNA encodes for SspB, SspC, SspD and SspA genes which are analogous to sip E BCD A (pages 781 abstract, Experimental procedures and page 784, figure 2). The prior art anticipates the claimed invention.

11. The Declaration under 37 CFR 1.131 filed on 4/24/00 is not sufficient to overcome the rejection of claims 46-86, 17 and 18 based upon 35 U.S.C. 102 (a) Hueck et al 1995, Kaniga et al 1995 and Hermant et al 1995 and 35 U.S.C. 102 (e) THE GENERAL HOSPITAL CORPORATION (WO95/02048).

The publication by Hueck et al is cited as evidence of conception and reduction to practice of the invention. However, this is not convincing for several reasons. First, while a printed publication can serve as evidence of conception of an

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invention, it does not serve as evidence of reduction to practice (In re Schlittler and Uffer (CCPA) 110 USPQ 304 1956). ^{only} More important, since the publication has several coauthors in addition to Dr. Samuel Miller, it does not serve as evidence of invention by the applicant prior to knowledge or publication of the invention by others. In addition, the claims are rejected as anticipated by the Hueck publication, and the declaration does not address this rejection.

12. No claims are allowed.

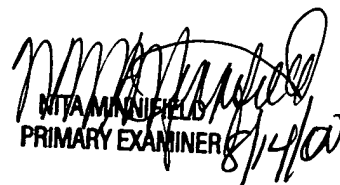
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

8/14/00


RITA MINNIELLO
PRIMARY EXAMINER 8/14/00